DOCKET NO.: HER-0050 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of :	Kuhner et al.	**Confirmation No.:**	9997
Appln. Serial No :	09/882,781	**Group No.:**	1645
Application Filing Date :	June 15, 2001	**Examiner:**	A. Navarro

For : CHEMICALLY-MODIFIED PEPTIDES, COMPOSITIONS, AND METHODS OF PRODUCTION AND USE

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Linda 3/27/03

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

RESPONSE TO OFFICIAL COMMUNICATION

The following remarks are submitted in response to the Official Communication dated February 25, 2003. Applicants request favorable consideration of the following remarks.

Claims 1-31 are pending in the present application and are subject to a Restriction Requirement mailed October 1, 2002. Applicants respectfully traverse the Restriction Requirement.

The Examiner asserts that Group I (claims 1-26, 30, and 31) and Group II (claims 27-29) are independent and distinct inventions. Applicants traverse the restriction requirement. To be fully responsive, however, Applicants hereby provisionally elect Group I (claims 1-26, 30, and 31) for prosecution and reserve the right to prosecute Group II (claims 27-29) in future continuing and/or divisional applications.

Two criteria must be met in order for a requirement for restriction to be proper: (1) the inventions must be shown to be independent and distinct; and (2) there must be a serious burden on the examiner, such as a showing of a separate classification, separate status in the art, or a different field of search. *See* MPEP § 803.

Applicants earnestly submit that Groups I and II should be joined. The claims of Group I are drawn generally to antimicrobial peptides having Formula I or Formula II. The claims of Group II are drawn to methods of preventing, inhibiting, or terminating the growth of at least one microbe by administering an antimicrobial amount of an antimicrobial comprising an antimicrobial peptide having Formula I or Formula II. The Examiner asserts that the Inventions of Groups I and II are distinct since "the methods of preventing the growth of microbes has been long practiced with materially different antibiotics such as penicillin." Office Action at 3. Applicants submit that the Examiner's reasoning is misplaced. The claims at issue are directed specifically to methods of preventing, inhibiting, or terminating the growth of at least one microbe by administering ***an antimicrobial peptide of Formula I or Formula II***. In other words, the invention as defined by claims 27-29 is incapable of being practiced without an antimicrobial peptide of Formula I or Formula II. Accordingly, Applicants assert that the Examiner has not established a *prima facie* showing that the inventions of Groups I and II are independent.

Additionally, Applicants submit that no serious burden on the Examiner exists, since a search of the claimed antimicrobial peptides would encompass a search of the claimed methods. The mere conclusory statement that the inventions are separately classified and constitute "recognized divergent subject matter" (Office Action at 3), without more, is insufficient to establish an undue burden on the Office.

Accordingly Applicants request reconsideration and withdrawal of the requirement for restriction among Groups I and II.

Restriction is further required within Groups I and II to "a single structure including specific substitutions." Office Action at 2. Applicants respectfully traverse the restriction requirement and submit that compounds of Formulas I and II should be jointly examined.

Applicants assert that no serious burden on the Examiner to search the antimicrobial peptides of both Formulas I and II has been established since the antimicrobial peptides recited in the claims are all classified in class 530, subclass 300. A search of the claimed structure would encompass a search of all the antimicrobial peptides set forth in the claims. As evidence that no serious burden on the Office exists, Applicants invite the Examiner's

attention to the claims of recently issued U.S. Patent No. 6,458,357 (containing claims reciting at least 6 different peptides), which was examined by the present Examiner.

Moreover, the Patent Office has decided *sua sponte* to aid the biotechnology industry and partially waive the requirement that claims drawn to biomolecules are automatically subject to requirement for restriction under 35 U.S.C. § 121 and 37 C.F.R. § 1.141. *See* MPEP § 803.04. Normally ten biomolecules constitutes a reasonable number. *See id.* Only in exceptional cases, such as where "a protein amino acid sequence reciting three dimensional folds" is claimed, will the reasonable number of biomolecules examined in an application be less than ten. *Id.* No exceptional circumstances warranting fewer than ten biomolecules in a single application are present in the instant case. Thus, joining of peptides having Formulas I and II is appropriate since it permits the examination of a reasonable number of biomolecules in the same application, accomplishes the goal of the Commissioner in aiding the biotechnology industry, and does not create an undue burden on the Office. Accordingly, Applicants request reconsideration and withdrawal of the restriction requirement.

Applicants note that the Examiner has indicated that a new Office policy has been issued whereby a single sequence or structure constitutes a reasonable number of inventions for examination in a single application even absent exceptional circumstances. **Applicants have been unable to locate any statutory or legal basis for such a policy and request that the Examiner provide evidence (e.g., a copy of the policy which preempts the Office policy noted above and legal or statutory basis therefor) of the Office policy upon which he relies.**

If the Examiner remains unwilling to consider rejoining peptides having Formula I or Formula II, Applicants urge the Examiner to consider joining peptides having Formula I or Formula II with R1 and R2 limited to C1 to C20 alkyl (including C3 to C6 cycloalkyl) or aromatic groups. This rejoinder would permit the examination of a reasonable number of biomolecules in the same application, would accomplish the goal of the Commissioner in aiding the biotechnology industry, and would not create an undue burden on the Office. Should the Examiner agree to rejoin peptides having Formula I or Formula II with R1 and R2 limited to C1 to C20 alkyl (including C3 to C6 cycloalkyl) or aromatic groups, Applicants would provisionally elect those species.

Alternatively, Applicants urge the Examiner to consider rejoining peptides having Formula I with R1 limited to a C1 to C9 alkyl (including cycloalkyl) or aromatic group with n = 2 or 3 and peptides having Formula II with R1 and R2 limited to C1 to C20 alkyl (including cycloalkyl) or aromatic groups with n = 1 or 2. Should the Examiner agree to rejoin peptides having Formula I with R1 limited to a C1 to C9 alkyl (including cycloalkyl) or aromatic group with n = 2 or 3 and peptides having Formula II with R1 and R2 limited to C1 to C20 alkyl (including cycloalkyl) or aromatic groups with n = 1 or 2, Applicants would provisionally elect those species.

Alternatively, Applicants urge the Examiner to rejoin peptides of Formula 1, wherein R1 is a C1 to C9 alkyl (including cycloalkyl) or aromatic group, n = 2 or 3, and the amino acids X_n are selected from Arg-Trp, Arg-Trp-Phe, Lys-Trp-Phe, Arg-Trp-Cys, and Lys-Trp-Cys and peptides of Formula 2, wherein R1 and R2 are C1 to C20 alkyl (including cycloalkyl) or aromatic groups, n = 1 or 2, and the amino acids X_n are selected from Arg, Lys, Arg-Arg, Arg-Gly, and Lys-Gly. Should the Examiner agree to rejoin peptides of Formula 1, wherein R1 is a C1 to C9 alkyl (including cycloalkyl) or aromatic group, n = 2 or 3, and the amino acids X_n are selected from Arg-Trp, Arg-Trp-Phe, Lys-Trp-Phe, Arg-Trp-Cys, and Lys-Trp-Cys and peptides of Formula 2, wherein R1 and R2 are C1 to C20 alkyl (including cycloalkyl) or aromatic groups, n = 1 or 2, and the amino acids X_n are selected from Arg, Lys, Arg-Arg, Arg-Gly, and Lys-Gly, Applicants would provisionally elect those species.

At a minimum, Applicants urge the Examiner to rejoin peptides of Formula 1, wherein R1 is a C6 to C9 alkyl (including cycloalkyl) or aromatic group, n = 2 or 3, and the amino acids X_n are selected from Arg-Trp, Arg-Trp-Phe, Lys-Trp-Phe, Arg-Trp-Cys, and Lys-Trp-Cys and peptides of Formula 2, wherein R1 and R2 are C6 to C11 alkyl (including cycloalkyl) or aromatic groups, n = 1 or 2, and the amino acids X_n are selected from Arg, Lys, Arg-Arg, Arg-Gly, and Lys-Gly. Should the Examiner agree to rejoin peptides of Formula 1, wherein R1 is a C6 to C9 alkyl (including cycloalkyl) or aromatic group, n = 2 or 3, and the amino acids X_n are selected from Arg-Trp, Arg-Trp-Phe, Lys-Trp-Phe, Arg-Trp-Cys, and Lys-Trp-Cys and peptides of Formula 2, wherein R1 and R2 are C6 to C11 alkyl (including cycloalkyl) or aromatic groups, n = 1 or 2, and the amino acids X_n are selected from Arg, Lys, Arg-Arg, Arg-Gly, and Lys-Gly, Applicants would provisionally elect those species.

To be fully responsive, however, Applicants hereby provisionally elect alkyl-CO-Arg-Trp-NH_2 (i.e., a peptide having Formula I wherein n = 2, R1 = a C1 to C9 alkyl (including cycloalkyl) group, and X_2 is Arg-Trp) for prosecution if the requirement for restriction is made final and reserve the right to prosecute the nonelected structures in future continuing and/or divisional applications.

CONCLUSION

Applicants believe this response to be fully responsive. Reconsideration and withdrawal of the requirement for restriction is respectfully requested. Applicants submit that the present claims meet all the requirements for patentability. The Examiner is respectfully requested to allow all the solicited claims. Applicants invite the Examiner to contact the undersigned at (215) 557-5908 to clarify any unresolved issues raised by this response.

Respectfully submitted,

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